

Notice of Allowability

Application No.

09/929,955

Applicant(s)

SALLBERG ET AL.

Examiner

Bao Qun Li

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 08/28/2003.
2. ☒ The allowed claim(s) is/are 21-25 and 28-36.
3. ☐ The drawings filed on _____ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.
5. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
 - (a) ☐ The translation of the foreign language provisional application has been received.
6. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. **THIS THREE-MONTH PERIOD IS NOT EXTENDABLE**

7. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
8. ☒ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☒ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☒ to Paper No. 12.
 - (b) ☐ including changes required by the proposed drawing correction filed _____, which has been approved by the Examiner.
 - (c) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No. _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the margin according to 37 CFR 1.121(d).

9. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|--|
| 1 <input type="checkbox"/> Notice of References Cited (PTO-892) | 5 <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2 <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6 <input checked="" type="checkbox"/> Interview Summary (PTO-413), Paper No. <u>14</u> |
| 3 <input checked="" type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No. <u>09/08/03</u> | 7 <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4 <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material | 8 <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9 <input type="checkbox"/> Other |

Bao Qun Li

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Eric Furman on February 18, 2004.

The application has been amended as follows:

Specification: In lines 23-24 of page 10: deleted "(See e.g., <http://msl.com/life/products/cerius2/index.html>)."

Claim 21 (amended):

In line 1 after "comprising" inserted --- nucleic acid molecule encoding ---

In line 2 after antigen inserted --- polypeptide ---

After "thereof" deleted ", wherein said viral antigen is a nucleic acid"

Claim 22 (amended): In line 2 after "said" deleted " viral antigen" and inserted --- nucleic acid molecule ---

Claim 28 (Amended): In line 2 after "acid" inserted --- molecule---

Claim 29 (twice amended): In line 2 after "acid" inserted --- molecule---

Claim 35 (amended): In line 2 deleted "peptide" and inserted --- polypeptide ---

Claims 21-25 and 28-36 are allowed.

1. The following is an examiner's statement of reasons for allowance: The claimed invention is allowed in view of Applicants response filed on August 15, 2003 in that the timely filed TD overcomes the double patenting rejection, and the amendment of claim 29 and argument overcome the 112 1st paragraph rejection and 103 obvious type rejection.

2. Applicants' amendment of claim 29 as a nucleic acid molecule comprising a fragment of the sequence of SEQ ID NO: 13 that encode an antigen peptide overcomes the rejection on broad scope of rejection on claim 29. Regarding to the claim 21, Applicants contested that "based on the understanding in the field as teaching from specification; one skill in the art would readily

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appreciate that the use of the whole HCV genome would be inoperable in an immunogenic composition, and thus one of skill in the art would not use the whole coding sequence of the HCV genome in an immunogenic composition. Therefore, the scope of allowed claim 21 and its dependent claims 22-25 only refer to a nucleic acid molecule encoding a viral antigen rather than any whole viral genome on the record.

3. The obvious type rejection under U.S.C. 103 is also overcome in view Applicants' instant response filed on August 15, 2003, in which applicants assert that the claimed invention is an unexpected result that is not the same as nor is it suggested by prior art.

4. First, Applicants particularly point out that the limitation of co- administration of rabivirin with an antigen, which differs from administration of rabivirin on the daily basis, cannot be ignored. Applicants asserted that all prior art cited by the prior art teach a method of daily administration of rabivirin, which function is to produce an immune-modulating effect by promoting Th1 and suppressing the Th2 response or shifting immunoglobulin IgG subclass production in patients. In contrast, Applicants' co-administration protocol results in a rise of total antibody titers to a specification antigen, but not just shift of IgG subclass or modulate the Th1/Th2 immune response balance. Therefore, Applicants concluded that the result produced by co-administration is not same as the daily therapy followed by periodic administration of an antigen. Co-administration of rabivirin with an antigen enhances an immune response, whereas, daily rabivirin therapy followed by a periodic immunization with an antigen promotes immune modulation (See page 13 of response).

5. Moreover, Applicants contend that disclosures of prior art teach away from the invention in that Tam teaches that rabivirin inhibits immune responses (See page 11 of response) and Hultgren et al. report that rabivirin treatment causes a transient drop in HCV-specific humoral responses and immune-suppressive in vitro and in vivo (page 12 of response).

6. In view above, all rejections are herein withdrawn.


7. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

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8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 571-272-0904. The examiner can normally be reached on 7:00 to 4:00.
9. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.
10. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Bao Qun Li

February 20, 2004


JAMES HOUSEL
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600
3/8/04